Form DQT-W: Worksheet for Designing Individual Field Trials under Reward® INAD 10-969

INSTRUCTIONS

1. Investigator must fill out Form DQT-W for each trial conducted under this INAD **before** actual use of Reward®. The Investigator is responsible that Form DQT-W is completed accurately.
2. Investigator should keep the original on file, and Fax a copy to the Study Monitor for review.
3. After review, the Study Monitor will fax a copy to the AADAP Office for assignment of the Study Number.
4. The AADAP Office will review the worksheet, and then fax the assigned trial Study Number to both the Investigator and Study Monitor, at which time the trial may be initiated.
5. **Note:** Both Investigator and Study Monitor should sign and date Form DQT-W.

SITE INFORMATION

Facility			
Address			
Investigator			
Reporting Individual (if not Investigator)			
Phone		Fax	

FISH CULTURE AND DRUG TREATMENT INFORMATION

Fish species to be treated			Disease to be treated	
Average fish weight (gm)			Average fish length (in)	
No. of fish per unit (e.g. 10,000 fish/raceway)				
Number of treated units			Number of treated fish	
Number of untreated control units			Number of control fish	
Anticipated date treatment will be initiated			Anticipated number of treatments	
Duration of drug treatment (hours)			Check type of treatment	__X__ Disease control
Check type of treatment method used			___ Flow through	___ Standing bath
Intended drug target dosage (mg/L)		2-18 mg/L	Estimated total amount of drug needed for proposed treatment (ml)	
		19-28 mg/L		
Drug manufacturer	**Syngenta**		Drug lot number	

STUDY DESIGN: Describe in detail the purpose of the clinical trial. For example you might compare dosage, treatment frequency, or treatment method (Flow-Through vs. Standing Bath). Study design must be carefully focused and lend itself to rigorous evaluation. If more space is required to describe study details, title additional page(s) "Study Design" and attach them to this Worksheet.

Study designed by _____

DISPOSITION OF TREATED FISH (Human Food Safety Considerations):

_____ Estimated time (days, months) from last treatment day to first possible harvest for human consumption

Check applicable box(es):

☐ Study Objective A - Withdrawal period of 5 days for channel catfish, muskellunge, tiger muskellunge, and northern pike.

☐ Study Objective B - Withdrawal period of 30 days for all other species.

☐ Investigator should initial here to indicate awareness that fish disposition must be in compliance with FDA-mandated withdrawal times as described in Section XV, page 15 of the Study Protocol.

WORKER SAFETY CONSIDERATIONS:

☐ Investigator should initial here to indicate that all personnel handling drug have read Material Safety Data Sheet for Reward® and have been provided protective equipment, in good working condition, as described in the MSDS.

Date Prepared: _____ **Investigator:** _____

Date Reviewed: _____ **Study Monitor:** _____

FORM DQT-1. Report on Receipt of Drug - Guide for Reporting Investigational New Animal Drug Shipments for Poikilothermic Food Animals

INSTRUCTIONS

1. Investigator must fill out Form DQT-1 **immediately** upon receipt of Reward®.
2. Investigator should keep the original on file, and send one copy to the Study Monitor for review.
3. Within 10 days of receipt, the Study Monitor should send a copy to the AADAP Office.
4. **Note:** Both Investigator and Study Monitor should sign and date Form DQT-1.

The sponsor, U.S. Fish and Wildlife Service, submits a notice of claimed investigational exemption for the shipment or delivery of a new animal drug under the provisions of Section 512 of the Federal Food, Drug, and Cosmetics Act. The following information is submitted in triplicate:

Name of Drug	**Reward®**	INAD Number	**10-969**
Proposed Use of Drug	Control mortality caused by bacterial gill disease and external flavobacteriosis in a variety of fish species		
Date of CVM Authorization Letter	October 31, 2007		
Date of Drug Receipt		**Amount of Drug Received**	
Drug Lot Number		**Study Worksheet Number**	
Name of Investigator			
Address of Investigator			
Location of Trial			
Pivotal Study (yes/no)		Non-pivotal Study (yes/no)	
Approximate Number of Treated Animals		**Approximate Number of Control Animals**	
Number of Animals Used Previously[1]			
Study Protocol Number	10-969		
Approximate dates of trial (start/end)			
Species, Size, and Type of Animals			
Maximum daily dose and duration	2-18 mg/L = 4 hr 19-28 mg/L = 1 hr		
Methods(s) of Administration	Immersion (static bath or flow-through treatment)		
Withdrawal Period	5 days for channel catfish, muskellunge, tiger muskellunge, and northern pike; 30 days for all other fish species		

[1] **To be filled out by the NIO**

Date Prepared: _____ **Investigator:** _____

Date Reviewed: _____ **Study Monitor:** _____

Date Reviewed: _____ **Sponsor:** _____

Form DQT-2: Chemical Use Log for Clinical Trials Under Reward® INAD 10-969

INSTRUCTIONS

1. Investigator should initiate a new form DQT-2 **immediately** upon receipt of each shipment of Reward®.
2. Form DQT-2 should be updated whenever drug is used, transferred, or discarded.
3. Investigator should save all copies of this form until the end of the calendar year, at which time they should maintain all originals on file and send one copy of the completed form(s) to their Study Monitor. Within 10 days of receipt, the Study Monitor will ensure accuracy and send a copy to the AADAP Office for inclusion in the permanent file.
4. **Note:** Both Investigator and Study Monitor should sign and date Form DQT-2.

Qty of Reward® from previous page (gal) _____ Facility _____ Reporting individual _____

Date	Amount of new Reward® received (ml)	Lot number of Reward® received	Study Number	Amount Reward® used in treatment (ml)	Reward® transferred (ml)	Reward® discarded (ml)	Reward® remaining on hand (ml)	Inventory by (initials)
	xxxx	xxxx						
	xxxx	xxxx						
	xxxx	xxxx						
	xxxx	xxxx						
	xxxx	xxxx						
	xxxx	xxxx						
	xxxx	xxxx						
	xxxx	xxxx						
	xxxx	xxxx						
	xxxx	xxxx						
	xxxx	xxxx						
	xxxx	xxxx						
	xxxx	xxxx						
	xxxx	xxxx						
	xxxx	xxxx						

Date Prepared: _____ **Investigator:** _____

Date Reviewed: _____ **Study Monitor:** _____

Form DQT-3: Results Report Form for Use of Reward® under INAD 10-969

INSTRUCTIONS

1. Investigator must fill out Form DQT-3 no later than 10 days after completion of the 10-day post-treatment observation period. Study Number must be recorded on all pages of Form DQT-3. Attach lab reports and other information.
2. If Reward® was not used under the assigned Study Number, fill out only the Site Information portion on this page, and skip to the end of page 3 and fill out only the "Negative Report" section.
3. Investigator should keep the original on file, and send a copy to the Study Monitor. Within 10 days of receipt, the Study Monitor should send a copy to the AADAP Office for inclusion in the permanent file.
4. **Note:** Both Investigator and Study Monitor should sign and date Form DQT-3.

SITE INFORMATION

Facility	
Reporting Individual	

TREATMENT INFORMATION AND SCHEDULE

Drug lot number		Total amount drug used (ml)	
Fish species treated		Reward® dosage used (mg/L)	
Treatment duration (hrs)		Number of treatments	
Disease treated		Disease diagnosed by	
Average fish weight (gm)		Average fish length (in)	
Number of fish per unit (e.g. 10,000 fish/raceway)			
Number of treated units		Total number of treated fish	
Number of control units		Total number of control fish	
Check type of treatment	____Flow through ____Standing bath		
Dates of treatment **(disease control)**	1st _____ 2nd _____ 3rd _____ 4th _____		

WATER QUALITY PARAMETERS

Ave pre-treatment temp (°F)		Dissolved Oxygen (mg/L)	
Ave treatment temp (°F)		pH	
Ave post-treatment temp (°F)		Hardness - $CaCO_3$ (mg/L)	

Daily Mortality Record

INSTRUCTIONS

1. Investigator should fill out the Daily Mortality Record as completely as possible.
2. Prior to initiation of the trial, fill out Rearing Unit ID, whether a rearing unit is Treated or Control, and the number of fish in each rearing unit.
3. Water temperature and individual tank mortality should be recorded on a daily basis.
4. If treatment is on 3 consecutive days, fill in only days 1-3 of the "treatment period" and proceed directly to day 1 of the "post-treatment period". If treatment is on 3 alternate days, fill in days 1-5 of the "treatment period" and proceed to day 1 of the "post-treatment period". If less than 3 treatments are used, proceed directly to day 1 of the "post-treatment period" after the final treatment. Please mark all treatment days with an asterisk.
5. Use additional copies of this form if more than 6 rearing units are involved in the trial.

FACILITY										
	Rearing Unit ID									
	Treated or Control									
	Number of Fish									
	Day	Date	Water Temp (F°)	Mortality	Mortality	Mortality	Mortality	Mortality	Mortality	Daily Observer Initials
Pre-treatment	1									
	2									
	3									
	4									
	5									
Treatment period	1									
	2									
	3									
	4									
	5									
Post-treatment period	1									
	2									
	3									
	4									
	5									
	6									
	7									
	8									
	9									
	10									

RESULTS: Describe in detail treatment results. Was treatment successful? If treatment did not appear to be successful, explain why not? Were there any mitigating environmental conditions that may have impacted treatment results? Were there any deviations from the Study Protocol?

Pathology Report: Attach pathology report to this form. Report should include: 1) a description of how the pathogen(s) was identified; 2) disease identification records that confirm the presence of the pathogen; and 3) the name and title of the individual performing the diagnosis.

Pathology Report included: ☐ pre-treatment ☐ post-treatment

Toxicity observations: Report any apparent drug toxicity including a description of unusual fish behavior.

DRUG DISCHARGE RESULTING FROM THIS TREATMENT: Use Addendum 2: Discharge Worksheet for calculations and attach completed Discharge Worksheet to this form. Enter the value from Addendum 2 step 3 in this space.

OBSERVED WITHDRAWAL PERIOD OF TREATED FISH:

Observed withdrawal period: _____ **5 days**; channel catfish, muskellunge, tiger muskellunge, and northern pike

Observed withdrawal period: _____ **30 days**; all other fish species

Estimated number of days between last treatment and first availability of fish for human consumption (ensure this time period meets the withdrawal period). _____

☐ **NEGATIVE REPORT** Reward® was not used at this facility under this Study Number during the reporting period. (Investigator should initial for negative reports as soon as the Study Number is known to be no longer needed or valid.)

Date Prepared: _____ **Investigator:** _____

Date Reviewed: _____ **Study Monitor:** _____

Discharge Worksheet - Reward®

Instructions: Use this Worksheet to calculate estimates of 1) the *maximum* amount of Reward® to be used for a single treatment of fish at your facility, and 2) the resulting concentration of Reward® in your total hatchery wastewater discharge.

Handy conversion factors: 1 part per million (ppm) = 0.0283 grams/cuft; or, 0.0038 grams/gallon.

Calculations:

Step 1 - Calculate the total flow of treated and untreated water during treatment period:

1a. Number of rearing units to be treated: _____

1b. Total water volume (at treatment flow rates) to these units during treatment period: _____ (gal.) or (cu ft.) of treated flow

1c. Total water volume to all other untreated units during treatment period: _____ (gal.) or (cu ft.) of untreated flow

1d Grand total hatchery discharge (Treated + Untreated) during treatment period: _____ (gal.) or (cuft.) of total flow

Step 2 - Calculate the amount of Reward® needed:

2a _____ gms = _____ * _____ * _____ ppm / _____
Amount | Vol. from line 1b | Conv. factor* | Desired dosage | % Active Ingredient

Step 3 - Calculate Reward® level in hatchery discharge during treatment period:

3a _____ ppm = _____ / (_____ * _____)
Disch. level | Amt. from line 2a | Total vol. (line 1d) | Conver. factor*

*If in gallons use 0.0038
If in cubic ft use 0.0283